UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, et al. *ex rel.* URI BASSAN, Plaintiffs, v. OMNICARE, INC., Defendant.	15 Civ. 4179 (CM)
UNITED STATES OF AMERICA, Plaintiff, v. OMNICARE, INC. and CVS HEALTH CORP., Defendants.	

UNITED STATES OF AMERICA'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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The United States of America (the "United States" or the "Government"), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, respectfully submits this memorandum of law in opposition to the motions by Defendants Omnicare, Inc. ("Omnicare") and CVS Health Corporation ("CVS") to dismiss the United States' Complaint-in-Intervention (the "Complaint").

PRELIMINARY STATEMENT

From 2010 until 2018, Omnicare violated the federal False Claims Act by fraudulently billing Medicare, Medicaid, and TRICARE for hundreds of thousands of non-controlled drugs dispensed without valid prescriptions to elderly and disabled residents of assisted living facilities, group homes, independent living facilities and other residential long-term care facilities.

Omnicare and its parent company, CVS, perpetrated this scheme by allowing Omnicare pharmacies to dispense prescription drugs to individuals living in residential facilities indefinitely, relying on expired prescriptions, prescriptions that were out of refills, and documents that were not valid prescriptions from doctors. In doing so, Omnicare—the country's largest long-term care pharmacy—disregarded its basic legal and professional obligations as a pharmacy. Omnicare managers exerted excessive pressure on poorly trained and overwhelmed pharmacy staff to dispense as many drugs as possible, as quickly as possible—without regard to whether the "prescription" received was limited to a certain number of refills, expired in a certain period of time, or was otherwise invalid.

Omnicare programmed its dispensing systems to ignore prescription refill and time limitations, and to continue dispensing based on stale prescriptions. Omnicare itself referred to this as "rolling over" old prescriptions. Rather than obtaining new prescriptions after old ones expired or ran out of refills—as required under governing law—Omnicare assigned new

prescription numbers to old prescriptions, and continued to push the drugs out the door, as if new prescriptions had been obtained. Omnicare dispensed drugs based on invalid prescriptions to tens of thousands of individuals living in more than 3,000 residential facilities. Many of these drugs—such as antipsychotics and anticonvulsants—treat serious, chronic conditions, can have dangerous side effects, and must be closely monitored by doctors.

Individuals living in residential facilities typically do not have access to in-house doctors to oversee their drug therapy. In contrast to skilled nursing facilities, which offer 24-hour medical care supervised by physicians, assisted living and other residential facilities generally offer limited medical care or none at all. Rather, individuals in residential facilities rely on their own doctors, outside of the facilities, to prescribe drugs, monitor their effectiveness, and determine whether drug therapies should be altered or stopped altogether. By repeatedly dispensing drugs without valid prescriptions to individuals in residential facilities, Omnicare put at risk the health and safety of individuals in residential facilities who took the same drugs for months and years without consulting their doctors.

In its motion to dismiss, Omnicare argues that even if its pharmacies routinely dispensed drugs without current, valid prescriptions, as the Complaint alleges, claims seeking reimbursement for such drugs would not be false. Indeed, Omnicare appears to take the surprising position that, at least until 2013, federal law permitted Omnicare to have federal healthcare insurance programs pay for drugs dispensed without valid prescriptions. Omnicare is wrong. Long before 2013, federal law required pharmacies to obtain a valid prescription in order to dispense a prescription drug. And federal statutes and regulations have long made clear that drug dispensations will not be reimbursed unless they are supported by valid prescriptions. Omnicare's claims for reimbursement were legally false because its drug dispensations violated

laws that clearly require valid prescriptions. Its claims were also factually false because they contained fabricated information that made it appear as though Omnicare had obtained a valid prescription when it had not.

Omnicare also argues that the Government has not adequately pleaded that the claims were false because state laws permit indefinite dispensations to assisted living and other residential facilities based on "medical orders," or, in the alternative, that state laws are so varied and ambiguous that Omnicare could not possibly be held liable for violating them. This, too, is a surprising argument from a pharmacy with approximately 160 locations across 47 states. To begin, Omnicare's argument assumes that its pharmacies consistently obtained valid "medical orders" from authorized prescribers. But this is contrary to the allegations in the Complaint that pharmacy staff accepted and dispensed drugs based on a wide-range of records from residential facility staff that were not generated by authorized prescribers and did not include elements of prescriptions or "medical orders," under any law applicable to any long-term care facility.

Moreover, Omnicare's argument that its conduct was permissible under state law is flatly contradicted by Omnicare's own compliance and operations executives, who repeatedly articulated their clear understanding that prescriptions for individuals in residential facilities could not be indefinite. Omnicare's own Compliance Department acknowledged that "in assisted living, that resident is living in their home, so their prescriptions come from the prescriber" after they "see the doctor and bring it back with them," and that the "rule of thumb is no less than annually should a new Rx or authorization be obtained for [assisted living facilities]." And Omnicare's own Operations Department recognized that "in the ALF and independent living setting we need to 'renew' prescriptions by contacting the doctor for a new RX once the existing RX is out of refills or remaining quantity." Consistent with this, Omnicare's *own written policies*

for ALFs explicitly provided that "[n]on-controlled medications may not be refilled 12 months after the original order has been filled and requires a new order from the Physician/Prescriber."

Omnicare's other arguments in support of its motion fare no better. Omnicare contends that that the Government's allegations of fraud are insufficient to meet the particularity requirements under Rule 9(b). But this argument completely overlooks the many detailed allegations in the Complaint as to each element of the fraudulent scheme, as well as the multiple lists attached as exhibits to the Complaint, which set forth the Omnicare pharmacies that dispensed drugs without valid prescriptions as well as the thousands of residential facilities that received those drugs. It also overlooks the exhibit to the Complaint cataloguing over 4000 specific false claims, which contains detailed information about the claims such as patient names, dates of service, and the names of the drugs dispensed without valid authorization.

Omnicare next resorts to mischaracterizing the Complaint to argue that the Government cannot establish scienter, casting the alleged fraudulent conduct as mere "system imperfections." But the Government's Complaint is not limited in this way. Rather, it alleges that Omnicare systematically dispensed drugs without valid prescriptions to people in assisted living and other residential facilities; that Omnicare's top management—including top management in its Operations and Compliance departments—knew that Omnicare systematically dispensed drugs without valid prescriptions; and that Omnicare did not begin to address the systematic illegal dispensing until after it became aware of the Government's investigation.

For its part, CVS contends that the Government cannot establish its involvement in the fraud by only alleging that CVS was the corporate parent of Omnicare beginning in 2015. This is yet another mischaracterization of the Complaint. In fact, the Complaint alleges that CVS assumed control over Omnicare's Operations and Compliance Departments, was directly

involved in the repeated identification of Omnicare's "rollover" dispensing problems, and failed to timely address them. These allegations are sufficient to establish CVS's liability.

Finally, Omnicare's arguments that the Government's reverse false claims and common law claims should be dismissed are conclusory and based on fundamental misunderstandings of law. Omnicare misstates the elements of the reverse false claim theory, and ignores the allegations showing that Omnicare failed to return payments received from federal healthcare programs for drugs dispensed without valid prescriptions after it realized these payments were for dispensations that were not reimbursable. Further, Omnicare's common-law arguments disregard established precedent recognizing that federal common law claims exist and upholding the validity of such alternative claims in False Claims Act healthcare cases.

BACKGROUND

A. Omnicare May Only Dispense Prescription Drugs Pursuant To Valid Prescriptions.

Federal law defines a prescription drug as a drug that "is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1). In light of this safety risk, federal law requires that pharmacies like Omnicare dispense prescription drugs only upon a valid prescription authorized by a medical practitioner licensed to administer the drug. *Id.*

Consistent with this federal mandate to ensure the safety of patients who are taking prescription drugs to treat medical conditions, Medicare and Medicaid statutes and regulations explicitly state that dispensations of prescription drugs not supported by valid prescriptions will not be reimbursed. *See* 42 U.S.C. §§ 1395w-102(e), 1396d(a)(12); 42 C.F.R. §§ 423.104(h), 440.120(a). In addition, CMS instructs that pharmacies undergoing audits of drug dispensations must produce signed prescriptions that authorize a specific number of refills or explicitly provide that the prescription is valid for a specific period of time. (Compl. ¶¶ 98, 252.) During those

audits, CMS rejects and refuses to pay for any prescriptions written more than twelve months before the date of the dispensation. (*Id.*)

B. Residential Facilities Do Not Provide Medical Supervision By A Prescriber.

Long-term care facilities are divided into two main categories: skilled and unskilled facilities. (*Id.* ¶¶ 72-83.) Skilled facilities are required to have a doctor on staff and medical care and supervision 24 hours a day. (*Id.* ¶¶ 72-73.) By contrast, unskilled facilities typically do not provide regular care by a staff physician or offer around-the-clock medical care. (*Id.* ¶¶ 74-83.)

The Complaint focuses on Omnicare's dispensations to people living in unskilled facilities, such as ALFs, independent living facilities, and adult or group homes that do not provide the 24-hour skilled medical care available at skilled facilities (together, "Residential Facilities"). (*See id.* ¶¶ 74-88.) Residential Facilities provide housing in conjunction with personal care and social services, rather than continuous skilled medical care. In particular, Residential Facilities do not typically offer regular medical supervision by a doctor responsible for residents' drug therapy. (*Id.* ¶¶ 74-83.) Instead, people living in Residential Facilities, like people living independently in their own homes, have to schedule visits with their own doctors who are unaffiliated with the Residential Facilities. (*Id.*) In light of this, prescriptions to people living in Residential Facilities are generally regulated in the same manner as prescriptions for people who live at home—the prescription must be limited by time and/or quantity, in order to trigger continued medical supervision while the patient is taking the prescription drug. (*Id.* ¶¶ 89-98.) The pharmacy thus cannot dispense beyond the limitations set forth in the prescription or imposed by law.

C. Prescriptions For People Living In Residential Facilities Must Contain Time And/Or Quantity Limitations.

State law defines what constitutes a valid prescription. (*Id.* ¶ 89.) Where patients do not have access to constant supervision by a physician (as happens in a hospital or skilled nursing facility), state laws typically provide that a prescription is only valid for a certain period of time and generally require prescriptions to specify the total quantity prescribed, which be expressed as a specified number of refills. (*Id.* ¶¶ 89-98, 189-95.) Such temporal and quantity limitations protect patients by ensuring that physicians (or other licensed prescribers) have the opportunity to regularly assess the safety and efficacy of their patients' drug therapy. (*Id.* ¶ 91, 96.)

Omnicare makes much of the uncontroversial fact that long-term care facilities offer varying levels of care, and that different states regulate prescriptions differently. (*See* Memorandum in Support of Omnicare's Motion to Dismiss Government's Complaint-in-Intervention ("Def. Br.") at 2-6.) But the Complaint does not allege the regulation of prescriptions or of long-term care facilities is uniform. Rather, it alleges that certain thresholds are well-established: Skilled facilities offer 24-hour medical supervision by an in-house physician, while unskilled facilities do not. (Compl. ¶¶ 72-83.) And state laws require that prescriptions for people who do not have access to round-the-clock medical care be limited in time or quantity to avoid dispensations in perpetuity without doctor supervision. (*Id.* ¶¶ 89-100.)

D. Omnicare Violated The Law By Dispensing Drugs Without Valid Prescriptions To Elderly And Disabled People In Residential Facilities.

As recounted by Omnicare pharmacists across the country, Omnicare management exerted tremendous pressure on pharmacy staff to dispense as many drugs as possible, as quickly as possible. (*See id.* ¶¶ 107-09.) One pharmacist reported that staff responsible for confirming that prescriptions were valid and that drugs were clinically appropriate were expected to review 60 to 65 prescription orders *every hour*. (*See id.* ¶109.) At the same time, Omnicare offered little

to no training on core dispensing requirements, including how to evaluate the validity of prescriptions; how to track the number of authorized refills; or how to track prescription expiration dates. (*Id.* ¶¶ 111-13.) And, during much of the Relevant Period, Omnicare's Compliance Department was understaffed and generally ineffectual. (*See id.* ¶¶ 114-20.)

1. Omnicare Dispensed Drugs Based On Invalid Documentation

Omnicare's constant pressure to get prescription drugs out the door, and its lack of training or compliance oversight, lead its pharmacies to routinely dispense drugs based on documents that were not valid prescriptions under *any* legal definition applicable to *any* long-term care facility. (*See id.* ¶¶ 174-84.) Such documents included lists of medications a resident was taking, Medication Administration Records, or faxed requests for medications from Residential Facility staff—none of which were generated or signed by prescribers. (*Id.*) Omnicare's overwhelmed and poorly trained pharmacy staff treated these documents as if they were valid prescriptions sufficient to trigger drug dispensations. (*Id.* ¶¶ 174-79.) As described below, once Omnicare pharmacy staff entered a "prescription" the dispensing systems without any refill or quantity limitation, the "prescription" could "roll over" and continue to trigger dispensations indefinitely. (*Id.* ¶¶ 174-75.)

2. Omnicare Dispensed Drugs Based on Expired Or Exhausted "Rollover" Prescriptions

Even when Omnicare pharmacies initially received valid prescriptions for individuals in Residential Facilities, Omnicare often disregarded the prescriptions' quantity and date limitations, thereby failing to track the prescription's expiration date or the number of authorized refills or total quantity prescribed. (*See id.* ¶¶ 142-87.) Instead of obtaining a new prescription after an old one expired or ran out of refills, Omnicare "rolled over" the same—now stale and no longer valid prescription—and continued dispensing. (*Id.*)

During the Relevant Period, Omnicare pharmacies used two different computer systems to record and track information on prescriptions and dispensations: OmniDX and Oasis. (*See id.* ¶ 121.) Both dispensing systems were programmed to deal with prescription expiration dates and refill limitations one of two ways: (1) the systems could track prescription dates and refills to prevent additional dispensations after expiration or refills were exhausted (until the pharmacy obtained a new valid prescription); or (2) the systems could "roll over" the old prescription and continue dispensing the drug. (*See id.* ¶¶ 121-41.)

"Rolling over" prescriptions meant that after twelve months of dispensing, Omnicare's dispensing systems assigned the old prescription a new number, and continued dispensing the drug. (*Id.*) In addition, if the dispensing systems were programmed to "roll over" prescriptions, the systems did not require quantity limitations to be entered. (*Id.* ¶ 132-34, 138.) Separately, when Omnicare "rolled over" a prescription, Omnicare bypassed its prescription review process, during which pharmacists confirmed that the prescription was valid, and that the drug was clinically appropriate for the patient by, among other things, checking for allergies, drug interactions, duplicate therapies, and contraindications. (*Id.* ¶ 125.)

These two options—tracking prescription expiration and refills or "rolling over" prescriptions—were meant to implement Omnicare's understanding of its dispensing obligations in skilled versus unskilled long-term care facilities. (*See id.* ¶¶ 127-38.) Thus, when Omnicare pharmacy staff entered a long-term care facility into Omnicare's computer dispensing systems (as the address for the person receiving the prescription drug), staff were supposed to select the option that corresponded to the category of long-term care facility. According to Omnicare's guidance, if a facility was a Residential Facility, Omnicare was supposed to program the system to track refills and prescription dates, and require a new prescription once refills were exhausted

or twelve had months passed. (*Id.* ¶¶ 127-38; *see also id.* ¶ 97.) If it was a skilled nursing facility, Omnicare was supposed to program the system to automatically "roll over" the prescription. (*Id.* ¶¶ 127-38.)

Even when pharmacy staff appropriately programmed Omnicare's OmniDX dispensing system to track refills and expiration dates for a Residential Facility, the system nevertheless "rolled over" prescriptions dispensed through its cycle fill program. (*Id.* ¶ 139-41.) In contrast to "demand" dispensing, whereby Omnicare dispensed drugs upon a specific request from the facility, Omnicare's cycle fill program allows the pharmacy to dispense drugs on a regular pre-determined schedule, usually for multiple residents of a facility, all on the same day. (*Id.* ¶ 139-40.) During most of the Relevant Period, the cycle fill program operated to override any prompt that would have prevented "rollover" prescriptions in Omnicare's OmniDX system, thereby allowing any prescription to "roll over" automatically, regardless of whether the pharmacy had programmed the system to track refills and expiration dates. (*Id.* ¶¶ 141, 162-69.) An Omnicare compliance manager described the cycle fill process as follows: "The DX System would allow refills to 'roll-over' if they ran out of refills. I'm not sure how this would ever be deemed an acceptable practice in a true ALF setting . . . . They need new scripts." (*Id.* ¶¶ 168.)

Contrary to law and its own policies, Omnicare disregarded its basic obligations as a pharmacy and programmed its systems to "roll over" prescriptions for residents of more than 3,000 unskilled Residential Facilities across the country. (*Id.* ¶¶ 149-73.)

E. Omnicare And CVS Knew That Prescriptions For Residential Facilities Were Only Valid For A Specific Number of Refills And/Or A Certain Amount Of Time.

Omnicare and CVS were well aware of Omnicare's obligation to obtain a current, valid prescription with time and quantity limitations for people in Residential Facilities. (*Id.* ¶¶ 90-98,

188-95.) And they knew that Omnicare could not just dispense drugs indefinitely based on "medication orders" lacking such limitations. . (*Id*.)

Omnicare's own Compliance Department recognized Omnicare's obligation:

- In February 2012, an Omnicare Compliance employee wrote: "In most states, assisted living and [facilities for the developmentally disabled] are considered retail so the retail rules would apply. In order for it to be a valid script, it would need to contain all the required elements. Patient and physician info, drug info, including qty and refills." (Compl. ¶ 191.)

- In June 2013, an Omnicare Compliance Officer wrote: "[F]or less than Skilled, we treat them like Retail and require signed prescriptions." (*Id.* ¶ 193.)

- In October 2013, an Omnicare Regional Compliance Officer responded that the "rule of thumb is no less than annually should a new Rx or authorization be obtained for ALF, and for SNF we try to get documentation for annual approval, but the Rx # can remain the same." (*Id.* ¶ 194.)

Similarly, Omnicare and CVS Operations executives recognized the obligation:

- In July 2012, Omnicare's Senior Director of Operations wrote: "All retail (think ALF…) … must follow 'retail' rx rules – actual # of refills and no rolling of the rx number." (*Id.* ¶ 220.)

- Also in October 2015, a Senior Manager in the Operations Department wrote: "[P]harmacies are not supposed to allow rollovers for ALF or any type of 'community' setting." (*Id.* ¶ 214.)

- In December 2015, Operations managers at Omnicare and CVS received an email from Omnicare's Business Capabilities Architect acknowledging that "[i]n the ALF and independent living setting we need to 'renew' prescriptions by contacting the doctor for a new RX once the existing RX is out of refills or remaining quantity" while "[i]n a SNF setting most of this renewal practice is accomplished seamlessly using signed physician order sheets or certified medication ordering systems." (*Id.* ¶ 195.)

Even Omnicare's written policies regarding ALFs made clear that "[n]on-controlled medications may not be refilled 12 months after the original order has been filled and requires a new order from the Physician/Prescriber." (*Id.* ¶ 97.)

F. Omnicare And CVS Knew That Omnicare Impermissibly "Rolled Over" Prescriptions And Dispensed Drugs To People In Residential Facilities Without Valid Prescriptions.

Omnicare and CVS were well aware that pharmacies across the country routinely dispensed prescription drugs without valid authorization. (*Id.* ¶¶ 196-225.) In fact, senior executives at Omnicare and CVS were alerted to the problem through: complaints from Omnicare's own pharmacies that Omnicare's systems dispensed drugs without valid authorization; internal and third-party audits showing that pharmacies regularly lacked documentation to justify dispensations; reports from Omnicare's own Compliance and Operations Departments; State Board of Pharmacy findings that Omnicare dispensed prescription drugs beyond what prescriptions authorized; and/or complaints from Residential Facilities that Omnicare was dispensing medications after refills had been exhausted. (*Id.*) For instance:

- A pharmacist who worked at an Ohio Omnicare pharmacy from 2011 until 2018 reported that she and others repeatedly complained to management that Omnicare was not tracking whether a prescription had any authorized refills before dispensing drugs to Residential Facilities. But Omnicare management ignored those complaints. (*Id.* ¶ 213; *see also id.* ¶¶ 212-14.)

- A 2012 internal audit raised as a "common issue[]" the fact that "[r]enewal physician orders are not consistently obtained due to the lack of an automated process to prevent the pharmacy from dispensing an order beyond 12 months." This internal report was sent to Omnicare's Chief Compliance Officer. (*Id.* ¶ 209; *see also id.* ¶¶ 208-11.) And during the Relevant Period, numerous insurance plans, including Medicare Part D sponsors, also conducted audits of Omnicare pharmacies to determine whether claims were supported by valid prescriptions. Omnicare Operations and Compliance managers were copied on many audit reports finding that up to 43% and 52% of the dispensations reviewed were not supported by valid authorization. (*Id.* ¶ 202; *see also id.* ¶¶ 202-07.)

- In April 2015, Omnicare's Compliance Department summarized Omnicare's "rollover" problem in an exchange among senior compliance officers: "An issue that I am running into more and more in multiple states concerns the ability of our systems to allow prescriptions to continue to roll after a year to a new prescription number without any documentation or pharmacist intervention." A compliance officer forwarded the email to the head of Omnicare's Third Party Audit group,

who responded that she had a "potential solution (*programmed last year*) but *no one is rolling it out now.*" (*Id.* ¶ 222 (emphasis added).)

- In 2015, the New Mexico Board of Pharmacy investigated Omnicare's Albuquerque pharmacy and found that "medications were being dispensed after refills had run out" and that "prescription medications were being dispensed pursuant to drug orders which did not have quantities, refills, and in some cases a prescriber's signature," which were "serious violations of the New Mexico Board of Pharmacy's statutes and regulations." CVS's Regulatory Affairs Department communicated directly with the Board of Pharmacy about these findings. (*Id.* ¶ 201.)

- In October 2015, a Maryland pharmacy manger complained that his staff was "finding that refills [for ALF residents] are going through without available refills and the [internal prescription number] is changed." In response, a Senior Manager in the Operations Department noted that pharmacies are "not supposed to allow rollovers for ALF or any type of 'community' setting. When she learned that "the entire facility is setup not to require refills," the Senior Manager wrote: "*I imagine the scope of this is huge*." (*Id.* ¶ 214 (emphasis added).)

- In 2016, an internal draft sales report sent to CVS and Omnicare operations managers pointed out that "both OmniDX and OASIS have significant gaps in automatically detecting and reviewing expiring [prescriptions] in the variety of processing areas where the last fill can be detected." (*Id.* ¶ 224.)

Despite being aware of the problem for years, neither Omnicare nor CVS began to address the "rollover" issue until after they became aware of the Government's investigation. (*Id.* ¶¶ 226-33.) And even then, they failed to return the amounts paid by Medicare, Medicaid, and TRICARE (together the "Federal Healthcare Programs") for the dispensations made without valid prescriptions. (*Id.* ¶¶ 283-86.)

G. CVS And Omnicare Caused The Submission Of Hundreds Of Thousands Of False Claims.

Omnicare's illegal dispensations resulted in the submission of hundreds of thousands of false claims to the Federal Healthcare Programs. (*Id.* ¶¶ 238-48.) In support of its claims for reimbursement, Omnicare was required to submit truthful and accurate information about each dispensation, which Omnicare gathered directly from its computer dispensing systems. (*Id.* ¶¶

240-44.) The claims information included the prescriber, the date the prescription was written, how the prescription was transmitted to the pharmacy (i.e., by telephone or fax), the number of refills authorized, the number of times the prescription has been filled, and information on drug coverage under the Federal Healthcare Program.

Because Omnicare's the dispensations were made pursuant to invalid, stale prescriptions, the information submitted to the Government Payors for the dispensation at issue—including the purported prescriber, how the prescription was purportedly received by the pharmacy, and the purported reimbursability of the dispensation—was false.[1] (*Id.* ¶¶ 244-45.) Omnicare's OmniDX dispensing system also automatically assigned artificially high numbers of authorized refills to "roll over" prescriptions—99 refills for Medicare Part D prescriptions—and manufactured new prescription dates (corresponding to the "rollover" date) whenever Omnicare "rolled over" expired prescriptions. (*Id.* ¶¶ 132-34, 244-45.) These fabricated dates and refill numbers were also reflected in the false claims submitted. (*Id.*) Government Payors relied upon the accuracy of this claim information in making payment decisions. (*Id.* ¶¶ 244-46.)

ARGUMENT

A. Omnicare's Claims Seeking Payment For Drugs Dispensed To Unskilled Residential Facilities Based On Invalid Prescriptions Were False.

Omnicare submitted hundreds of thousands of claims for payment for drugs dispensed pursuant to prescriptions that had expired or run out of refills, or pursuant to no prescription at all. Those claims were false.

[1] "Government Payors" refers to the Federal Healthcare Programs, as well as contracted Medicare Part D plans, Medicaid Managed Care Organizations, and pharmacy benefit managers who paid Omnicare claims for reimbursement. (Compl. ¶ 14.)

There are two main categories of false claims under the False Claims Act ("FCA"): factually false claims and legally false claims. A claim is legally false where the defendant has certified compliance with a particular statute, regulation, or contractual term that is material, despite the defendant having violated it. *Mikes v. Straus*, 274 F.3d 687, 696-97 (2d Cir. 2001). By contrast, a claim is factually false where the defendant submitted "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.*

Omnicare contends that the Complaint fails to sufficiently allege that its claims seeking payment for drugs dispensed based on expired, exhausted, or otherwise invalid prescriptions contravened Omnicare's certifications of compliance with federal law. Specifically, Omnicare argues that before 2013, the Federal Healthcare Programs did not limit coverage to drugs dispensed based on valid prescriptions, and that in any event, state prescription laws permitted Omnicare's indefinite dispensations. (Def. Br. at 4-5, 9-14.) Omnicare is wrong. Omnicare's claims were legally false because federal law required valid prescriptions in order to dispense prescription drugs and receive reimbursement throughout the Relevant Period. Moreover, Omnicare ignores the Complaint's allegations that Omnicare's claims were also factually false, as they contained false information about prescriptions that purportedly existed and purportedly supported the dispensations.

1. Omnicare's Claims Were Legally False.

Omnicare's claims to the Federal Healthcare Programs were legally false, because its drug dispensations flouted Omnicare's express and implied certifications that it complied with federal and state law requiring valid prescriptions. (Compl. ¶ 247.) "Express" legal falsity arises where a government program requires participants to explicitly state that they have complied with certain statutes or requirements. *Mikes*, 274 F.3d at 698. Medicare required Omnicare to

certify to compliance with federal laws and regulations. (Compl. ¶¶ 35-42.) And Medicaid required Omnicare to certify compliance with federal and state law.[2] (*Id.* ¶¶ 49, 50.)

"Implied" legal falsity arises "when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Universal Health Servs., Inc. v. U.S.*, 136 S. Ct. 1989, 1995 (2016). Omnicare's claims for reimbursement by TRICARE were impliedly legally false, as Omnicare submitted claim for prescription drugs without disclosing that the dispensation violated federal law requiring a valid prescription. (Compl. ¶¶ 240-46.)

(a) Omnicare Violated Federal Law Requiring Valid Prescriptions.

It its motion, Omnicare erroneously suggests that the only federal law requiring valid prescriptions for dispensations is Medicare regulation 42 C.F.R. § 423.104(h), which Omnicare points out did not take effect until January 1, 2013. (*Id.* at 10.) Apparently, Omnicare believes that, before 2013, Omnicare was entitled to reimbursement from the Federal Healthcare Programs for drugs dispensed without valid prescriptions. (*Id.*) Indeed, Omnicare contends that in 2013, Medicare's "guidance" suddenly "evolved" to require valid prescriptions. (*Id.* at 4.) This is nonsense.

As CMS made clear when proposing and issuing the regulation, "[s]ince the inception of the Part D program, we have consistently maintained that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable State law."

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[2] Inexplicably, Omnicare claims that "there is no suggestion [in the Complaint] that Omnicare expressly certified compliance with any state prescription laws." (Def. Br. at 10.) In fact, the Complaint alleges that Medicaid providers like Omnicare must "affirmatively certify, as a condition of payment of the claims submitted to Medicaid for reimbursement, compliance with applicable federal and state laws and regulations." (Compl. ¶ 50.)

76 Fed. Reg. 63,018, 63,059 (Oct. 11, 2011). Indeed, as Omnicare itself acknowledges in a footnote (*see* Def. Br. at 10 n.6), the regulations were issued merely "to remove any doubt as to the appropriate source of law to consult when determining whether a prescription is valid." 77 Fed. Reg. 22,072, 22,139 (Apr. 12, 2012).

In fact, federal law has long made clear that a prescription drug may only be dispensed "upon a written prescription of a practitioner licensed by law to administer such drug"; or "upon an oral prescription" that is "reduced promptly to writing"; or "by refilling any such written or oral prescription if such refilling is authorized by the prescriber." *See* 21 U.S.C. § 353(b)(1); *see also U.S. v. Ihenacho*, 716 F.3d 266, 270 (1st Cir. 2013) (interpreting 21 U.S.C. § 353(b)(1) to require "valid prescriptions"); *U.S. v. Riccio*, 43 F. Supp. 3d 301, 308 (S.D.N.Y. 2014) (noting that case law has defined a "prescription" under section 353(b)(1) "as one issued in the usual course of professional practice and for a legitimate medical purpose" (quoting *U.S. v. Smith*, 573 F.3d 639, 652 (8th Cir.2009)); (Compl. ¶¶ 66-67, 70). And Medicare has consistently defined a "covered part D drug" to mean, in part, "a drug that may be dispensed only upon a prescription," 42 U.S.C. § 1395w-102(e). Consistent with this, during audits of pharmacies like Omnicare, CMS has required valid prescriptions specifying the number of refills authorized or the period of time the prescription was valid. (Compl. ¶¶ 252-53.)

Separately, Medicaid provides that coverage extends only to "prescribed drugs." *See* 42 U.S.C. § 1396d(a)(12). By its terms, this provision means that Medicaid will not reimburse claims for drugs dispensed pursuant to invalid prescriptions. Omnicare objects to the relevance of this Medicaid statute, arguing that it does not set forth a "definition of the term, the required documentation, or reference to any state law." (Def. Br. at 5.) This is silly. Omnicare is a pharmacy licensed to dispense prescription drugs; it should know what a valid prescription is. *Cf.*

U.S. v. Oz, No. 13 Cr. 273, 2016 WL 1183041, at *10 (D. Minn. Mar. 28, 2016) (finding that physicians can be "expected to know the statutes and regulations that applied to [the highly regulated pharmacy and medical fields]"). Indeed, as alleged, Omnicare did know—throughout the Relevant Period—that valid prescriptions for people in Residential Facilities are defined by state law to require prescriptions limited in time and/or quantity. (*See* Compl. ¶¶ 191-92, 197-201, 216, 231-32; *see also* 42 C.F.R. § 440.120(a).)

Thus, the Complaint alleges that Omnicare's dispensations violated federal law, in contravention of its express and implied certifications, rendering Omnicare's claims legally false. *Cf. Sturgeon v. Pharmerica Corp.*, No. 15 Civ. 6829, 2020 WL 586978, at *19 (E.D. Pa. Feb. 2, 2020) (holding that dismissal of FCA claim was not appropriate where plaintiff alleged that long-term care pharmacy "routinely" substituted "alternative drugs without physician's consent" such that "the dispensation would not be pursuant to a valid prescription and the pharmacy could not legally seek reimbursement from Medicare or Medicaid").

(b) State Law Does Not Permit Indefinite Dispensing Of Drugs To People In Residential Facilities

Omnicare routinely dispensed prescription drugs based on stale, invalid prescriptions or no prescriptions at all, in violation of state law. (Compl. ¶¶ 89-98; 142-84.) Omnicare disputes this, arguing that most states permitted Omnicare to dispense drugs to individuals in Residential Facilities for an indefinite period based on "medication orders" without time or quantity restrictions. (Def. Br. at 11-13.) This is meritless.

First, Omnicare's litigation position is contrary to the pharmacy's own clearly and consistently articulated position that prescriptions for individuals in Residential Facilities were required to contain time and quantity limitations:

- As an Omnicare Regional Compliance Officer explained, "in skilled, the nurses will transmit to the pharmacy chart orders from the prescriber, and so the facility

is providing the orders as in a hospital." On the other hand, "[i]n assisted living, that resident is living [in] their home, so their prescriptions come from the prescriber. So the patient might see the doctor and bring it back with them, and then a caregiver might send it over to the pharmacy or the physician just directly sends a prescription to the pharmacy."

- Compliance Department acknowledged that the "rule of thumb is no less than annually should a new Rx or authorization be obtained for ALF," and that "[i]n most states, assisted living and [facilities for the developmentally disabled] are considered retail so . . . for it to be a valid script, it would need to contain . . . qty and refills." (*See* Compl. ¶¶ 191, 194; *see also id.* ¶¶ 192, 193.)

- Omnicare's Operations Department recognized that "[i]n the ALF and independent living setting we need to 'renew' prescriptions by contacting the doctor for a new RX once the existing RX is out of refills or remaining quantity" and that ALFs "must follow 'retail rules – actual # of refills and no rolling of the rx number." (*Id.* ¶¶ 195, 220).

- In 2018, Omnicare asked pharmacists using Oasis to determine whether unskilled facilities were programmed in accordance with state law. In response, Omnicare's own pharmacists identified more than 500 Residential Facilities that had been improperly set up to not track refill and prescribed quantity limited, thereby allowing prescriptions to be dispensed "in perpetuity." Thereafter, Omnicare management finally took steps to address the "rollover" problem in Oasis. (Compl. ¶¶ 231-32.)

- Omnicare's own written policies for ALFs provided that "[n]on-controlled medications may not be refilled 12 months after the original order has been filled and requires a new order from the Physician/Prescriber." (*Id.* ¶ 97; *see also id.* ¶ 128.)

Consistent with this, Omnicare's audit department acknowledged that CMS audits required valid prescription documentation, which meant signed prescriptions that authorized a specific number of refills or explicitly provided that the prescription was valid for a specific period of time. (*Id.* ¶ 252.) And CMS rejected any prescription orders written more than twelve months before the date of the dispensation. (*Id.*)

Omnicare's current argument that it was legally permitted to dispense prescription drugs to people in Residential Facilities indefinitely based on "medication orders" is entirely manufactured. Indeed, one is left wondering why Omnicare went through the trouble of having

dispensing systems capable of preventing dispensations once refills were exhausted or prescriptions expired—and instructing Omnicare employees to use that capability for Residential Facilities—if that was never required. In fact, it was required, and Omnicare repeatedly acknowledged it.

Despite this, Omnicare devotes three pages to misleading citations of state-law in an apparent effort to argue that state law permitted Omnicare to dispense drugs to people in Residential Facilities indefinitely based on old purported "medication orders."[3] (Def. Br. 11-13.) This argument also fails.

To begin, Omnicare assumes that its pharmacies consistently obtained valid medication orders from authorized prescribers. But this is contrary to allegations in the Complaint that Omnicare dispensed drugs based on documents that do not constitute valid prescriptions under *any* federal or state definition, including medication lists, medication requests, and Medical Administration Reports that were not generated or signed by prescribers. (*See* Compl. ¶¶ 174-84.) Thus, state laws regulating prescriptions and drug orders in different long-term care settings are largely irrelevant to the question whether Omnicare's dispensations in this case were illegal.

In any event, Omnicare's state law citations do not support its position. For instance, Omnicare cites a Wyoming regulation for the proposition that drug orders need not specify drug quantities. (*See* Def. Br. at 12 (citing Wyo. Admin. Rules 059.0001.15 § 4)). But a subsection of that *very same regulation* makes clear it applies to a "long term care facility" or "LTCF," which

[3] Omnicare contends only that the laws of 28 states and Washington, D.C. permitted Omnicare's indefinite "rollover" dispensations of prescription drugs to people in Residential Facilities. (*See* Def. Br. Ex. 1.) As such, Omnicare does not dispute that its dispensing practices violated state law with respect to over 1,000 unskilled facilities across 15 states.

explicitly "*does not include* adult day care facilities, home health agencies, or *assisted living facilities*." Wyo. Admin. Rules 059.0001.15 § 4(a) (emphasis added).

Similarly, Omnicare cites Indiana Code section 25-26-13-2, which applies to "health care institutions," to argue that Indiana permits Omnicare to dispense drugs to ALF residents based on drug orders that do not specify the quantity prescribed. (*See id*. at 13.) But that statute provides that a "drug order" must set forth, among other information, "*the amount to be dispensed either in quantity or days*."[4] Ind. Code § 25-26-13-2 (emphasis added). And, consistent with this, Indiana law separately provides that a prescription or drug order for a non-controlled drug "may not be refilled *except in the manner designated on the prescription or drug order* or *by the authorization of the practitioner*." Ind. Code § 16-42-19-12 (emphasis added).

And even if some state statutes did permit drug orders without specified quantities at Residential Facility, Omnicare incorrectly asserts that those states also permit medication orders to be effective in perpetuity. (*See* Def. Br. at 13 (asserting—without citation—that "these states also permit pharmacies to honor prescriptions for residents of long-term-care facilities for more than one year from the date the order was written").) That is incorrect. For instance, Omnicare cites a Minnesota statute for the proposition that drug orders need not specify quantity. (Def. Br. at 12.) And yet Omnicare's "rollover" dispensations still violated a Minnesota regulation providing that "[n]o prescription drug order may be filled or refilled more than 12 months after the date on which it was issued." Minn. R. 6800.3510. Similarly, Omnicare cites a New York regulation in support of its position (Def. Br. 12), but disregards another that provides: "(1) A written order may not be refilled unless the practitioner has indicated the number of allowable

[4] Under Indiana Code section 25-26-13-2, the amount to be dispensed need not be specified if the amount is otherwise "specified by individual institutional policy or guidelines."

refillings on the order. (2) No written order for drugs may be refilled more than six months after the date of issuance, nor more than five times within a six month period," N.Y. Comp. Codes R. & Regs. Tit. 18 § 505.3. (*See also, e.g.*, Def. Br. at 12 (citing Neb. Rev. Stat. § 38-2810, but ignoring *id.* § 38-2870, which provides: "All medical orders shall be written, oral, or electronic and shall be valid for the period stated in the medical order," except that "if the medical order is for a [non-controlled] drug or device, such period shall not exceed twelve months from the date of issuance at which time the medical order shall expire").)

2. Omnicare's Claims Were Factually False.

In its motion, Omnicare does not even address the Complaint's allegations that it submitted hundreds of thousands of claims that contained fabricated information about prescriptions purportedly authorizing each of the dispensations for which Omnicare sought reimbursement. (*See* Compl. ¶¶ 238-46).

As established, Omnicare's dispensations violated federal law, because they were based on invalid prescriptions. Yet, when seeking payment from Government Payors for the drugs dispensed, Omnicare falsely reported information indicating that the pharmacy had actually obtained valid new prescriptions for its dispensations. (*Id.* ¶ 243-45.) Such information included the supposed prescriber; the date the purported prescription was written; the means by which the purported prescription was received by the pharmacy; the number of refills purportedly authorized; the number of times the purported prescription had been filled; and information regarding the reimbursability of the drug under the Federal Healthcare Plan. (*Id.*)

This information submitted in support of the claim for payment was generated directly from Omnicare's computer dispensing systems, which "rolled over" old prescriptions and restated the expired prescription information while assigning new prescription numbers. (*Id.*) Omnicare's OmniDX system also automatically assigned artificially high numbers of authorized

refills (including 99 refills for Medicare drugs) to prescriptions that "rolled over," and automatically generated new prescription dates for the expired prescriptions that corresponded with the "roll over" date. (*Id.* at 132-34, 244-45.) This fabricated information was included in Omnicare's claims for payment. (*Id.*) Thus, the information in Omnicare's claims for "rollover" dispensations was factually false because a current, valid prescription supporting the dispensation claimed did not exist: No prescriber authorized the "rollover" dispensation; no prescription was written on the "rollover" date; no prescription supporting that dispensation was received by the pharmacy; no "rollover" refills had been authorized; and the drug dispensation was not reimbursable. (*Id.* at 244-45.)

B. The Complaint Sufficiently Pleads Particular Fraudulent Claims.

The allegations in the Complaint more than satisfy the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. Rule 9(b) requires that a plaintiff set forth details of the fraudulent scheme and information identifying particular false claims submitted to the government. *U.S. ex rel. Kester v. Novartis Pharm. Corp.* ("*Kester I*"), 23 F. Supp. 3d 242, 255, 257-58 (S.D.N.Y. 2014). But "[i]n cases where the alleged fraudulent scheme is extensive and involves numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct." *Id.* at 258 (internal quotation marks and citation omitted). Rather, "plaintiffs can plead the submission of thousands of claims with particularity by providing example claims which are representative of those arising from the fraudulent scheme." *U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 526 (S.D.N.Y. 2014) (quoting *Kester I*, 23 F. Supp. 3d at 259) (internal quotation marks omitted).

"The point of Rule 9(b) is to ensure that there is sufficient substance to the allegations to both afford the defendant the opportunity to prepare a response and to warrant further judicial

process." *U.S. ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 87 (2d Cir. 2017) (quoting *U.S. ex. rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 125 (D.C. Cir. 2015)). A complaint is sufficient if it "provide[s] the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue." *Kester I*, 23 F. Supp. 3d. at 258; *see also United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 616-17 (S.D.N.Y. 2013) (finding that the Government satisfied Rule 9(b) by pleading "ten examples of insurance claims identified by . . . case number," which gave the defendant sufficient notice by enabling it "to infer with reasonable accuracy the precise claims at issue by examining the representative samples of the broader claim of claims").

The Complaint provides Omnicare with fair notice of the fraudulent scheme and false claims at issue in this case. As alleged, Omnicare pharmacies violated the FCA by billing the Federal Healthcare Programs for hundreds of thousands of drugs dispensed to individuals living in over 3,000 Residential Facilities without valid prescription. (Compl. ¶¶ 142-271.) The Complaint explains how prescriptions improperly "rolled over" (*id.* ¶¶ 142-87), it details Defendants' knowledge of the fraud (*id.* ¶¶ 185-233), and it sets forth the specific information in each claim that is false (*id.* ¶¶ 238-48). Further, the Complaint attaches exhibits specifically listing: (*i*) 1,256 Residential Facilities that received "rollover" dispensations from pharmacies that used the OmniDX dispensing system, and the specific Omnicare pharmacies that dispensed drugs to those facilities (*see id.* Ex. 1); (*ii*) 510 Residential Facilities that received "rollover" dispensations from pharmacies that used the Oasis dispensing system, and the specific pharmacies that dispensed to those facilities (*see id.* Ex. 2); and (*iii*) 1,476 Residential Facilities that received "rollover" dispensations through via the cycle fill program (*see id.* Ex. 4). Finally, the Complaint also contains detailed information about more than 4,000 example false claims,

including the name and social security number for each beneficiary; the name, address, and identification number of each beneficiary's Residential Facility; the name of the Omnicare pharmacy that dispensed the drugs; the names of the drugs that were dispensed without a valid prescription; and the dates of each illegal dispensation. (*See id.* ¶¶ 258-71 & Ex. 5.)

Tellingly, Omnicare never contends that it lacks sufficient information to respond to the Complaint. Because it cannot. The Complaint's allegations are plainly sufficient to allow Omnicare to reasonably infer which other false claims are at issue in this case, and that is all that Rule 9(b) requires. *See Kester I*, 23 F. Supp. 3d at 258; *Wells Fargo*, 972 F. Supp. 2d at 616; *see also U.S. ex rel. Bledsoe v. 66. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007) ("[T]he concept of a false or fraudulent scheme should be construed as narrowly as is necessary to protect the policies promoted by Rule 9(b)."); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999).

Additionally, Omnicare concedes that the Complaint adequately pleads a fraudulent scheme whereby Omnicare submitted false claims to the Government over a multi-year period. Rather, Omnicare lodges objections on the margins, arguing that the Complaint fails to plead the "Oasis theory" with particularity; that it fails to plead false claims for each of the nine years in the Relevant Period; and that it fails to plead false Medicaid and TRICARE claims. (Def. Br. at 14-17.) Omnicare is wrong on all counts.

1. The Complaint Contains Sufficient Detail As To The Oasis System.

To begin, as the Complaint makes clear, Omnicare's "Oasis" system is merely one of two computer systems used by Omnicare pharmacies to "roll over" stale or invalid prescriptions as part of Omnicare's fraudulent scheme. (Compl. ¶¶ 121-22.) The Oasis system is not materially different from Omnicare's other dispensing system, OmniDX. Indeed, Omnicare used both systems to perpetuate its fraud in the same manner—by "rolling over" invalid prescriptions to

continue dispensing drugs without authorization. (*See id.* ¶¶ 127-34.) Omnicare's use of Oasis is part and parcel of the fraudulent scheme at issue in this case, for which the Government has provided extensive information. (*Id.* ¶¶ 146, 149-51, 158-61, 174-87, 195, 212-13, 224, 243-45.)

Moreover, the Complaint contains ample detail about Oasis in particular, including how Oasis tracked prescription dates and refills if a facility was properly categorized as an unskilled Residential Facility (*id.* ¶¶ 135-37); when Oasis allowed prescriptions to "roll over" (*id.* ¶¶ 135, 138); Omnicare pharmacy staff's complaints about the Oasis "rollover" (*id.* ¶¶ 159-60, 213); Omnicare senior management's knowledge about the Oasis "rollover" issue (*id.* ¶¶ 223-24); Omnicare's failure to fix the Oasis "rollover" issue for years (*id.* ¶¶ 230-32); and a list of 510 Residential Facilities that received "rollover" dispensation from pharmacies that used the Oasis system. (*id.* ¶¶ 158, 161, Ex. 2).

Omnicare also argues that the Government's 4,000+ example claims are not representative of the "Oasis theory" because they relate to prescriptions "dispensed by pharmacies that used the OmniDX system." (Def. Br. at 15.) Bu as already addressed, OmniDX and Oasis both "rolled over" prescriptions in the same manner; there is no material difference between claims generated by these systems for purposes of Rule 9(b). Indeed, Omnicare itself identified the "rollover" problem as shared by "both OmniDX and OASIS." (*See* Compl. ¶ 224; *see also id.* ¶ 195). The Government's choice of a sample that includes claims generated using OmniDX—the system used by the majority of Omnicare pharmacies—does not deny Omnicare fair notice about any aspect of this case, particularly where the Complaint also includes lists of "rollover" Residential Facilities incorrectly coded as skilled in both Oasis and OmniDX.[5] (*See*

[5] Omnicare's argument that the Government's failure to include specific types of claims in its representative set of claims is "'particularly noteworthy' given its direct access to the relevant claims information" (Def. Br. at 15), is misleading. While the Government may be able to access

Compl. ¶¶ 152-67 & Exs. 1, 2); *Cf. U.S. ex rel. Tahlor v. AHS Hosp. Corp.*, No. 08 Civ. 2042, 2014 WL 4494793, at *4 (D.N.J. Sept. 10, 2014) ("[C]ourts have accepted, for purposes of a motion to dismiss [under Rule 9(b)], that a defendant violating the FCA in one location was engaging in the same conduct in another location.").

2. The Complaint Sufficiently Identifies Sample False Claims For The Relevant Period.

Nor does the Complaint need to identify false claims from every year of the time period alleged in the Complaint. While sample false claims must be within the overall period of the fraudulent scheme, there is no requirement that they cover the entire period from end-to-end. *See U.S. ex rel. Kester v. Novartis Pharm. Corp.* ("*Kester VII*"), No. 11 Civ. 8196 (CM), 2015 WL 109934, at *23 (S.D.N.Y. Jan. 6, 2015). Neither of the cases Omnicare cites supports its attempt to narrow the scope of this case in this formalistic manner. (*See* Def. Br. at 16.) In *U.S. v. Comstor Corporation*, the relator's claim was dismissed because the relator provided "*no* particularized allegations" and *no* examples of false statements from any part of the time period at issue. 308 F. Supp. 3d 56, 92 (D.D.C. 2018) (emphasis added). Similarly, in *U.S. ex rel. Seal 1 v. Lockheed Martin Corporation*, the circuit affirmed the dismissal of a relator's complaint where he provided almost no factual allegations whatsoever about the false claims and alleged "on information and belief, that Lockheed submitted progress bills and milestone bills for payment and that[,] on information and belief, the [government] paid these claims." 429 F. App'x 818, 820 (11th Cir. 2011).

Here, unlike in *Comstor* and *Lockheed Martin*, the Government has provided particularized allegations that cover the entire period at issue. For example, the Complaint

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claims data as a general matter, in order to allege that specific individual claims for reimbursement are false, the Government requires records only in Omnicare's possession.

describes details of the fraudulent scheme as observed by witnesses who worked at Omnicare in 2010 and 2011 (*see* Compl. ¶¶ 10, 107, 109, 112, 178, 213, 225), as well as witnesses who worked there in 2017 and 2018 (*see id.* ¶¶ 10, 107, 109, 112, 144, 173, 178, 213). And as the Complaint explains, although the OmniDX "rollover" problem was finally addressed in 2016, Omnicare inexplicably failed to address the identical issue in Oasis until 2018. (*See id.* ¶¶ 230-33.) Omnicare has fair notice of the Government's case against it with respect to the entire time period at issue. *See U.S. ex rel. Escobar v. Universal Health Servs.*, 780 F.3d 504, 509, 515 (1st Cir. 2015), *vacated on other grounds*, 136 S. Ct. 1989 (2016) (identification of false claims over two-year period as to one patient sufficient to satisfy Rule 9(b) as to claims submitted for other patients for fraudulent scheme over six-year period); *U.S. ex rel. Manion v. St. Luke's Reg'l Med. Ctr., Ltd.*, No. CV 06-498-S-EJL, 2008 WL 906022, at *3 (D. Idaho Mar. 31, 2008) ("To require Plaintiffs to provide specific information as to exactly when alleged violations took place over a multi-year time frame such as this would make Rule 9(b) carry more weight than it was meant to bear.").

3. The Complaint Provides Sufficient Notice of False Claims to Medicaid and TRICARE.

Finally, Omnicare erroneously argues that the Government is required to include specific examples of Medicaid and TRICARE claims. (Def. Br. at 16.) Again, such formalism is not required where the Complaint provided detailed allegations concerning the fraudulent scheme, and more than 4,000 examples of false claims submitted to Government Payors generally. Indeed, in *Kester VII*, this Court rejected the defendants' attempts to demand that the relator provide sample claims as to each government program, noting that "[t]here is no logical stopping point for such an argument. The [d]efendants could just as easily demand that the Relator provide sample claims for each drug with respect to each program during each year of the

kickback scheme. Rule 9(b) is simply not that rigid in False Claims Act cases." *Kester VII*, 2015 WL 109934, at *23; *see U.S. v. TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 WL 750720, at *15 (S.D.N.Y. Feb. 22, 2016) ("Providing sample claim information for one program . . . is a sufficient basis for the Court to infer that similar claims were submitted to the other named government programs.").

The only case that Omnicare cites, *U.S. ex rel. Mooney v. Americare, Inc.*, No. 06 Civ. 1806, 2013 WL 1346022, at *7 n.6 (E.D.N.Y. Apr. 3, 2013), which the *Kester VII* court considered and declined to follow, *see Kester VII*, 2015 WL 109934, at *23, is unconvincing and inapposite. In that case, the plaintiff pleaded 12 example false Medicare claims and only that there was "no reason to doubt that the claims were submitted to state Medicaid programs." *Mooney*, 2013 WL 1346022, at *6. Here, the Complaint contains specific allegations about Omnicare's false Medicaid and TRICARE claims—that a large percentage of residents at the facilities Omnicare served were Medicare, Medicaid, or TRICARE beneficiaries, and Omnicare allowed prescriptions to "roll over" in Residential Facilities with over 10,000 Medicaid beneficiaries. (*See* Compl. ¶¶ 14, 156; *see also id.* ¶ 167.)

In sum, "there is no mandatory 'checklist' of information a plaintiff must provide to satisfy Rule 9(b)." *Kester VII*, 2015 WL 109934, at *23. Because the Complaint affords Omnicare fair notice of the actions that the Government alleges caused false claims to be submitted for payment, the Government has met its burden to plead with particularity the fraudulent scheme and the false claims at issue.

C. The Complaint Sufficiently Pleads That Omnicare Acted Knowingly.

The Government has also sufficiently pleaded scienter. The text of the FCA expressly provides that it does not require "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). Rather, the FCA imposes liability for, among other things, "knowingly" submitting a false claim.

31 U.S.C. § 3729(a)(1)(A)-(B). "[K]nowing" means "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Rule 9(b) permits scienter to be alleged "generally." Fed. R. Civ. P. 9(b).

The Complaint's allegations easily satisfy the FCA's scienter requirement: Omnicare knew that its pharmacies needed current valid prescriptions to dispense drugs to individuals in Residential Facilities. (Compl. ¶¶ 97-98, 188-95, 252-53.) It also knew that Omnicare pharmacies across the country nevertheless dispensed drugs at such facilities without valid authorization. (*Id*. ¶¶ 196-233.) Omnicare managers were repeatedly alerted to that fact by multiple sources: findings of state boards of pharmacy that Omnicare dispensed drugs beyond what prescriptions allowed, third-party audits showing that Omnicare pharmacies regularly lacked the documentation required for their dispensations, internal audits showing that Omnicare pharmacies dispensed drugs without valid prescriptions, complaints from Omnicare pharmacy personnel that Omnicare dispensed drugs without valid prescriptions, and complaints from Residential Facilities themselves that Omnicare continued to dispense drugs after prescriptions had expired. (*Id.* ¶¶ 196-218.)

Despite years of awareness of this widespread issue, further evidenced by Omnicare's numerous internal discussions about it and its seriousness (*id.* ¶ 219-25), Omnicare did not address the issue until after the company learned of the Government's investigation (*id.* ¶ 226-33). And this was not Omnicare's first federal investigation: in 2012 Omnicare paid $50 million to the Government to settle claims related to similar conduct—its dispensing of controlled substances to long-term care patients without valid prescriptions. (*Id.* ¶ 118.) Considered together, these allegations establish that Omnicare submitted false claims and made false

statements to Government Payors with actual knowledge or, at the very least, with deliberate ignorance or reckless disregard. *See TEVA Pharm.*, 2016 WL 750720, at *28.

Omnicare mischaracterizes the Complaint's allegations, arguing that the Complaint merely pleads that it did not "establish the Government's preferred form of 'organization infrastructure,'" that its "systems did not operate flawlessly," and that it "lacked adequate 'formal training.'" (Def. Br. at 17-18.) This attempt to downplay the seriousness of Omnicare's failures as a nationwide pharmacy is unconvincing. Omnicare put tremendous pressure on understaffed pharmacies to process high volumes of prescriptions making it virtually impossible for them to ensure that drugs were only dispensed based on current, valid prescriptions (*see* Compl. ¶¶ 107-09); Omnicare provided little to no training on how to evaluate the validity of prescriptions or how to use Omnicare's dispensing systems (*see id.* ¶¶ 110-13); and Omnicare's dispensing systems did not just "not operate flawlessly," they systematically defrauded the Government through the submission of hundreds of thousands of false claims (*see id.* ¶¶ 121-38). Moreover, Omnicare's argument deliberately ignores the parts of the Complaint that describe in detail Omnicare's *knowledge* over many years that its pharmacies were dispensing drugs without valid prescriptions and its failure to fix this problem. (*See* Compl. ¶¶ 196-233); *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 2011 Civ. 962, 2013 WL 2303768, at *5 (N.D. Ga. May 17, 2013) (complaint's allegations that defendants had actual or constructive knowledge that prescriptions at issue were off-label satisfy relator's burden to plead FCA scienter).

Omnicare separately argues that the Government may not assert "[a] theory of nationwide fraud based upon discrete conduct by a few local-level employees" (Def. Br. at 20), and cannot rely on "events occurring in discrete Omnicare pharmacies between August 2012 and 2015 in which prescription-documentation issues were allegedly raised to local Omnicare supervisors" to

plead scienter (*id.* at 19). To the contrary, the Complaint alleges that Omnicare's senior management—at the highest levels—was aware of the problems, including its Chief Compliance Officer, Chief Audit Officer, Vice President of Operations, Senior Director of Operations, numerous other senior Operations and Compliance managers, and CVS's Director of Regulatory Affairs. (*See* Compl. ¶¶ 7-9, 11, 169, 173, 177, 185, 189, 191-96, 200-02, 209, 211, 214, 216-17, 219-25, 227, 229-30.) The Complaint does not describe isolated incidents at a handful of pharmacies but rather a system-wide failure involving the vast majority of Omnicare pharmacies that affected elderly and disabled individuals in thousands of Residential Facilities across the country. (*See id.* ¶¶ 1-14, 101-233 & Exs. 1-4.) And Omnicare's argument that the Complaint "does not allege that any Omnicare employee intentionally evaded [Omnicare's] systems" (Def. Br. at 17), misses the point—Omnicare's systems were *designed* to permit widespread dispensing based on stale, invalid prescriptions. (*See* Compl. ¶¶ 121-41.)

Omnicare is also wrong that the Complaint must identify specific Omnicare employees by name. (Def. Br. at 19.) The cases that Plaintiff cites are inapposite as they address whether individuals who submitted false claims or made false statements must be identified in order to satisfy Rule 9(b)'s requirement that specific claims be pleaded with particularity. *See U.S. ex rel. Vallejo v. Investronica, Inc.*, 2 F. Supp. 2d 330, 337 (W.D.N.Y. 1998); *U.S. ex rel. DeCarlo v. Kiewit/AFC Enters.*, 937 F. Supp. 1039, 1050 (S.D.N.Y. 1996). As such, they provide no support for Omnicare's argument that the Complaint's references to witnesses with operations or compliance responsibilities are insufficiently specific.[6] In any case, the Complaint need not have

[6] By providing the job title, pharmacy location (for pharmacy-based staff), and/or approximate dates of employment in the Complaint, the Government has provided sufficient information for Omnicare to identify the witnesses, who are its own current or former employees, some of whom were deposed with Defendants' counsel present.

identified any specific person, even those who submitted false claims, by name because "[w]here a plaintiff 'has alleged that a corporation has committed fraudulent acts, it is the identity of the corporation, not the identity of the natural person, that the plaintiff must necessarily plead with particularity.'" *Wells Fargo*, 972 F. Supp.2d at 618 (quoting *Bledsoe*, 501 F.3d at 506); *see also Heath*, 791 F.3d at 125; *U.S. v. Huron Consulting Grp., Inc.*, No. 09 Civ. 1800 (JSR), 2011 WL 253259, at *2 & n.3 (S.D.N.Y. Jan. 24, 2011); *Omnicare*, 2013 WL 2303768, at *6.

Finally, the Complaint adequately pleads scienter with respect to the entire Relevant Period. Omnicare argues that because certain "discrete incidents" mentioned in the Complaint "all occurred after August 2012," there is no basis to infer fraudulent intent before that time. (Def. Br. at 20-21.) But Omnicare overlooks numerous events described in the Complaint that demonstrate that Omnicare acted knowingly "throughout the Relevant Period." (Compl. ¶ 196.) These include:

- The testimony of "an Omnicare Operations manager who consulted with Omnicare pharmacies across the country . . . that *from 2006 until 2016*, she identified numerous pharmacies that allowed prescriptions . . . to 'roll over,' and each time, she advised the pharmacy's General Manager and her supervisor" (*id.* ¶ 225 (emphasis added));

- A 2012 internal audit in which Omnicare found that the failure to obtain prescription renewal order after 12 months was a "common issue[] in this and other similar operational audits in 2012" (*see id.* ¶ 209);

- The repeated complaints of an Omnicare pharmacist who worked in Ohio from 2011 until 2018 that ALFs were being set up incorrectly in Oasis causing problems tracking refills (*id.* ¶ 213); and

- The notification of senior Omnicare Operations management in July 2012 that the cycle fill program was bypassing safeguards designed to ensure that dispensations were supported by valid prescriptions issues and that there was a fix that was not being implemented (*see id.* ¶ 220).

See also supra Part B (discussing particularized allegations in 2010 and 2011). This is more than enough factual detail to allege that Omnicare acted "knowingly" beginning in 2010, particularly as scienter need only be pleaded generally. *See Kester I*, 23 F. Supp. 3d at 251.

D. The Complaint States A Claim Against CVS For Its Direct Involvement In The False Claims.

CVS's defense to liability rests upon its fundamental mischaracterization of the Complaint: that "the Complaint mentions CVS only to allege that it was the corporate parent of Omnicare beginning in 2015." Memorandum in Support of Motion to Dismiss by CVS Health Corporation ("CVS Br." at 1.) This is flatly untrue.

The Complaint sets forth numerous specific allegations detailing CVS's involvement and participation in the fraudulent submission of claims for drug dispensations without valid prescriptions. For instance, the Complaint alleges that, shortly after acquiring Omnicare, "CVS assumed an active role in overseeing Omnicare's operations, including pharmacy dispensing practices and systems" (Compl. ¶ 21); that after acquiring Omnicare, CVS "assumed control over Omnicare's Operations and Compliance departments, overseeing Omnicare pharmacy dispensing practices, policies, and systems" (*id.* ¶ 186); that CVS's Director of Regulatory Affairs and audit team were made aware of and were directly involved in responding to the illegal dispensing practices at the heart of the FCA claims here as early as 2015 (*id.* ¶¶ 8, 173, 201, 224); that CVS's Vice President and Chief Audit Executive directed Omnicare management to "design and implement a monitoring program to assess pharmacy compliance with required refill authorizations" (*id.* ¶ 173); and that in 2017, CVS's Senior Director of Internal Operations LTC inquired what needed to be done to prevent "rollovers" in the Oasis system(*id.* ¶ 230).

These allegations are plainly sufficient to establish CVS's liability under the FCA. *See U.S. ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc.*, No. CV 15-13065-PBS, 2018

WL 4539684, at *5 (D. Mass. Sept. 21, 2018) (denying motion to dismiss parent corporation because "[a] parent may be liable for the submission of false claims by a subsidiary where the parent had direct involvement in the claims process"); *U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 62-63 (D.D.C. 2007) (denying motion to dismiss parent where there was some evidence of parent's participation in false claims and where parent's oversight of fraudulent billing evinced "reckless disregard" as to falsity of claims); *cf. also U.S. v. Bestfoods*, 524 U.S. 51, 67 (1998) (holding that parent company could be held liable as "operator" under CERCLA where it made "decisions about compliance with environmental regulations"); *Morgan v. Baker Hughes Inc.*, 728 F. App'x 850, 855 (10th Cir. 2018) (upholding jury's finding of parent corporation's liability where "[e]vidence presented at trial also suggested that [the parent] exercised control over the aspect of the subsidiary's action that is in dispute . . . and did not merely offer generalized policies").

CVS's proffered cases are distinguishable or inapposite. (*See* CVS Br. at 5-6.) Certain of these cases involve complaints in which plaintiffs made vague allegations of "defendants'" activities without distinguishing which defendant undertook which activity. *See U.S. ex rel. Takemoto v. The Hartford Fin. Servs. Grp., Inc.*, 157 F. Supp. 3d 273, 281 (W.D.N.Y. 2016) (complaint "group[ed] related corporations together without differentiating as to the involvement of each," and attorney acknowledged that "exactly which companies did which things is far from clear at this point"); *U.S. ex rel. Ahumada v. Nat'l Ctr. for Employment of the Disabled*, No. 1:06-CV-713, 2013 WL 2322836, at *3 (E.D. Va. May 22, 2013) (pleadings against numerous companies under headings of "all defendants" or groups of defendants insufficiently particular). And CVS's citation to *U.S. v. Bornstein*, 423 U.S. 303, 312 (1976), is misplaced, because it dealt with the plaintiff's failure to attribute acts to appropriate entities at the damages calculation

stage, rather than whether the plaintiff had adequately pleaded participation sufficient to survive a motion to dismiss. Here, the Complaint specifically sets forth CVS's role in the fraudulent conduct. (*See, e.g.*, Compl. ¶¶ 8, 173, 186, 201, 224, 230.)

CVS argues that the Complaint does not suffice to pierce the corporate veil (CVS Br. at 4-5), and indeed the Government does not proceed on a veil-piercing or alter-ego theory. Yet in arguing that CVS did not directly participate in the false claims at issue, CVS returns to cases involving precisely such veil-piercing claims in an attempt to conflate the test for veil-piercing or alter-ego liability with that of direct participation. (*See* CVS Br. at 6 (again citing *U.S. ex rel. Raffington v. Bon Secours Health Sys., Inc.*, 285 F. Supp. 3d 759, 769 (S.D.N.Y. 2018) (applying "complete domination" veil-piercing test); *U.S. ex rel. Hussain v. CDM Smith, Inc.*, No. 14 Civ. 9107 (JPO), 2017 WL 4326523, at *11 (S.D.N.Y. Sept. 27, 2017).) These cases have little to say regarding direct participation. *See, e.g.*, *Hockett*, 498 F. Supp. 2d at 60-63 (rejecting veil-piercing liability but denying motion to dismiss due to parent's direct participation).

The Complaint's numerous allegations of CVS's involvement and participation in Omnicare's illegal drug dispensations to Residential Facilities, which must be credited at the pleading stage, are further bolstered by the fact that CVS has already acknowledged its obligation to ensure Omnicare's compliance with all Federal Healthcare Program requirements. On October 11, 2016, in connection with the resolution of another FCA case alleging Omnicare kickbacks to skilled nursing facilities, CVS entered into a Corporate Integrity Agreement ("CIA") with HHS's Office of Inspector General ("HHS OIG"), in which it agreed that, for a period of five years, CVS would comprehensively oversee all institutional pharmacy services.

(*See generally* Gov. Br. Ex. 1 (the "CVS CIA").)[7] As defined in the CVS CIA, institutional pharmacy services ("IPS") explicitly includes "all operations . . . conducted under the Omnicare . . . name[], relating to institutional pharmacy services, including, but not limited to, the furnishing of pharmacy or patient care items or services to long-term care facilities." (*Id.* at 2.) The CVS CIA provides that CVS shall appoint a "Chief Compliance Officer" for CVS as well as a "Compliance Officer for IPS Operations," and that these officers "shall be *employees and members of senior management of CVS Health*." (*Id.* at 4 (emphasis added).) These officers shall be responsible for, *inter alia*, "overseeing all compliance matters related to CVS's IPS Operations" and "developing, implementing, and enforcing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements." (*Id.* at 5.) Moreover, the CVS CIA specifically provides that "CVS Health shall create systems and procedures reasonably designed to ensure the accurate . . . dispensing, and billing of the drug name and manufacturer to the Federal health care programs of prescription drugs dispensed or used in connection with the IPS Operations [*i.e.*, including Omnicare's operations]." (*Id.* at 17-18.) CVS's disclaiming of responsibility now is entirely inconsistent with the terms of its agreement with HHS OIG.

E. The Government Properly States A Claim For Relief Under The Reverse False Claims Provision Of The FCA.

Count III of the Complaint asserts a claim for relief against under 31 U.S.C. § 3729(a)(1)(G). (Compl. ¶¶ 283-86.) This provision is referred to as the "reverse false claims"

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[7] The Court may consider the CIA because it is incorporated by reference in the Complaint at Paragraph 120. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152-53 (2d Cir. 2002). Alternatively, the Court may take judicial notice of the CIA. *See* CVS CIA, *available at* https://oig.hhs.gov/fraud/cia/agreements/CVS_Health_Corporation_10112016.pdf; *see also Wells Fargo Bank N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 166 (S.D.N.Y. 2015) (holding that "it is clearly proper to take judicial notice" of "documents retrieved from official government websites").

provision of the FCA "because the financial obligation that is the subject of the fraud flows in the opposite of the usual direction." *U.S. ex rel. Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370, 379 (S.D.N.Y. 2015) (quoting *U.S. ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1195 (10th Cir. 2006)). Omnicare's argument seeking dismissal of this claim is unavailing, as it largely relies on case law interpreting a pre-amendment version of the statute.

Omnicare recites the wrong elements for the Government's cause of action under § 3729(a)(1)(G), when it asserts that the Government must plead that the defendant "used a false statement to avoid or decrease that obligation." (Def. Br. at 22.) Before 2009, the FCA prohibited the use of "a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7) (2006). But the reverse false claims provision was amended in 2009 as part of the Fraud Enforcement and Recovery Act ("FERA") to close a "loophole" allowing defendants to avoid liability for "actions to conceal, avoid, or decrease an obligation" to return "money or property that is knowingly retained by a person even though they have no right to it." S. Rep. No. 111-10, at 13-14 (2009). After FERA, the operative version of the reverse false claims provision gives rise to liability for anyone who "knowingly conceals or *knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government*." 31 U.S.C. § 3729(a)(1)(G) (emphasis added).

Thus, after FERA, a "false statement is no longer a required element" under the second prong of § 3729(a)(1)(G). *U.S. ex rel. Customs Fraud Investig., LLC v. Victaulic Co.*, 839 F.3d 242, 255 (3d Cir. 2016). Rather, "[t]he elements of a violation under the second prong of the reverse-FCA provision are that the defendant (1) concealed or improperly avoided or decreased an obligation to pay the government and (2) did so knowingly." *U.S. ex rel. Ormsby v. Sutter Health*, No. 15 Civ. 1062, 2020 WL 1590521, at *29 (N.D. Cal. Mar. 16, 2020).

Next, Omnicare wrongly contends that the Government has not identified the source of its obligation to repay funds to which it was not entitled. (Def. Br. at 22-24.) In fact, the Complaint specifically alleges that Omnicare's repayment obligation flows from the overpayment provision added to the Social Security Act by the Patient Protection and Affordable Care Act (the "PPACA"), 42 U.S.C. § 1320a-7k(d). (*See* Compl. ¶ 24.) That provision defines an "overpayment" as "any funds that a person receives or retains under [the Medicare and Medicaid statutes] to which the person, after applicable reconciliation, is not entitled." *Id.* § 1320a-7k(d)(4)(B). The provision also requires that an overpayment be returned within 60 days after it is identified, *id.* § 1320a-7k(d)(2), and provides that the continued retention of an overpayment beyond this 60-day deadline is an "obligation" for purposes of the FCA, *id.* § 1320a-7k(d)(3).

Once Omnicare knew its pharmacies had systematically dispensing drugs to people in Residential Facilities without valid prescriptions for years, it also knew that Omnicare had received payments from Medicare or Medicaid that were overpayments resulting from non-reimbursable drug dispensations. (*See* Compl. ¶¶ 196-233.) At that point, and thereafter, Omnicare was required to return (within 60 days) the overpayments under the PPACA. *See Kane*, 120 F. Supp. 3d at 396 (concluding that 42 U.S.C. § 1320a-7k(d) and congressional intent "contradict[ed] Defendants' argument that the Government has failed to allege an obligation with regard to the federal government"); *see also Ormsby*, 2020 WL 1590521, at *29.

Omnicare cannot ignore the inquiries by state pharmacy boards, internal and external audits, and pharmacist and facility complaints, all of which raised red flags with respect to its dispensing practices for prescription medications at Residential Facilities. (*See* Compl. ¶¶ 8-11, 196-225.) Several of the audits—which reviewed only a sample of Omnicare's dispensations—specifically found that Omnicare had received overpayments, in amounts totaling hundreds of

thousands of dollars, because of invalid prescriptions. (*See id.* ¶¶ 203-05.)[8] Indeed, it was only after Omnicare became aware of the Government's investigation that it implemented company-wide changes to its systems to prevent expired or exhausted prescriptions from illegally "rolling over" in the future. (*See id.* ¶¶ 226-32.) Yet still Omnicare failed to return the overpayments for the past dispensations without valid prescriptions or even to investigate further to try to quantify the overpayments resulting from dispensations without valid authorization. (*Id.* ¶ 233.) Based on the foregoing, the Government has sufficiently pleaded that Omnicare had a repayment obligation to the United States.

Omnicare also contends that its liability here is a "contingent obligation[] that cannot form the basis for reverse-FCA liability." (Def. Br. at 23.) But Omnicare again ignores the fact that in FERA, Congress specifically defined "obligation" as "an established duty, *whether or not fixed*, arising," *inter alia*, "from statute or regulation, or *from the retention of any overpayment*." 31 U.S.C. § 3729(b)(3) (emphases added); *see also U.S. ex rel. Tra v. Fesen*, 403 F. Supp. 3d 949, 965 (D. Kan. 2019) (rejecting defendant's argument that the relevant "obligation is not established until after litigation," and concluding that "by statute, a Medicare provider is required to return an overpayment to the government").[9]

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[8] *See Kane*, 120 F. Supp. 3d at 383-95 (denying motion to dismiss claims under § 3729(a)(1)(G) where the defendants were on notice that certain claims submitted to the Government might contain erroneous billing codes); *U.S. ex rel. Keltner v. Lakeshore Medical Clinic, Ltd.*, No. 11 Civ. 0892, 2013 WL 1307013, at *3-*4 (E.D. Wis. Mar. 28, 2013).

[9] Legislative history states that Congress was responding to "confusion among courts that have developed conflicting definitions of the term 'obligation,'" and cites the case on which Omnicare relies to illustrate the narrow interpretation that FERA intended to correct. S. Rep. No. 111-10, at 14 & nn.9-10 (citing *Am. Textile Mfrs. Inst. v. The Ltd., Inc.* ("*ATMI*"), 190 F.3d 729, 736 (6th Cir. 1999)). "FERA expressly rejected *ATMI*'s narrow interpretation of the FCA's reverse false claims provision in favor of a more broadly inclusive definition." *Customs Fraud*, 839 F.3d at 253-54. Nor is this a case involving a "duty that is dependent on a future discretionary act," like a contingent Government penalty. *See U.S. ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 505 (3d Cir. 2017).

Finally, the Government's claim under § 3729(a)(1)(G) is not duplicative of its § 3729(a)(1)(A) claim, but a separate, valid legal theory that the Government has pleaded in the alternative. *See U.S. ex rel. Ortiz v. Mount Sinai Hosp.* ("*Mount Sinai I*"), No. 13 Civ. 4735 (RMB), 2015 WL 7076092, at *12-13 (S.D.N.Y. Nov. 9, 2015) (denying motion to dismiss reverse false claims count pleaded in the alternative). Courts have "routinely held that the Government may plead alternative theories of liability in FCA cases." *U.S. ex rel. Landis v. Tailwind Sports Corp.*, 308 F.R.D. 1, 8 (D.D.C. 2015); *see also U.S. ex rel. Kester v. Novartis Pharm. Corp. ("Kester VI")*, No. 11 Civ. 8196 (CM), 2014 WL 4401275, at *12 (S.D.N.Y. Sept. 4, 2014) (permitting alternative pleading of common law claims).[10] This is so "even if different claims seek relief for the same injury, so long as there is ultimately only one recovery." *U.S. ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 505 F. Supp. 2d 20, 24 (D.D.C. 2007).[11]

Permitting alternative pleading is necessary because Omnicare's conduct may give rise to differing causes of action, based on facts developed in discovery. For instance, Omnicare argues that between 2010 and April 2012 (prior to the investigations and audits detailed in the Complaint (*see* Compl. ¶¶ 196-225)), it submitted claims without knowledge that they were false, such that the claims do not fulfill the knowledge requirement of § 3729(a)(1)(A). (*See* Def. Br. at 20-21.) And if Omnicare's argument were correct, these claims would give rise to a cause

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[10] While certain courts have ruled that these causes of action are duplicative, *see, e.g., U.S. ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 514-15 (E.D. Pa. 2010), many of these cases rely on pre-FERA law or fail to recognize the plaintiff's right to plead in the alternative under Rule 8. *See U.S. v. Guzzone*, 273 F.2d 121, 123 (2d Cir. 1959) (in FCA action, Government "may set forth alternative legal bases for recovery").

[11] Omnicare cites *U.S. ex rel. Ortiz v. Mount Sinai Hosp.* ("*Mount Sinai II*"), 256 F. Supp. 3d 443, 458 (S.D.N.Y. 2017), for the proposition that these claims are duplicative. That decision, however, was at the summary judgment stage, and the relator's claims under § 3729(a)(1)(A) survived the defendant's summary judgment motion. Earlier in the same case, however, Judge Berman permitted claims under § 3729(a)(1)(G) to proceed past a motion to dismiss, *see Mount Sinai I*, 2015 WL 7076092, at *12-13, as the Court should here.

of action under the reverse false claim provision, because Omnicare knowingly failed to reimburse the Government long after realizing that these claims had been submitted without current, valid prescriptions. (*See* Compl. ¶¶ 24, 185-187, 219-225, 226-233.) *See Graves v. Plaza Med. Centers, Corp.*, No. 10 Civ. 23382, 2015 WL 13736639, at *5 (S.D. Fla. Dec. 7, 2015) (reverse false claim was "an alternative basis of liability" if the defendant's basis for wrongful claims for payment "were merely mistakes and not fraudulent"), *report and rec. adopted*, 2016 WL 11440123 (S.D. Fla. Jan. 5, 2016).

F. Omnicare's Motion to Dismiss the Government's Common Law Claims Should Be Denied.

The Complaint also raises claims for payment by mistake of fact and unjust enrichment. *See* Counts IV and V (Compl. ¶¶ 287-92). As Omnicare concedes—the Supreme Court has held that the "Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid." *U.S. v. Wurts*, 303 U.S. 414, 415 (1938). "No statute is necessary to authorize the United States to sue in such a case. The right to sue is independent of statute." *Id.* (quotation marks omitted).

Omnicare contention that there has been no federal common law since *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938), is simply incorrect. It is clear that "federal law governs questions involving the rights of the United States arising under nationwide federal programs." *U.S. v. Kimbell Foods, Inc.*, 440 U.S. 715, 726 (1979). Since *Erie*, the Supreme Court has reaffirmed that federal common law continues to exist in "narrow areas," such as "those concerned with the rights and obligations of the United States." *Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 641 (1981); *see also U.S. v. Gen. Dynamics Corp.*, 19 F.3d 770, 773 (2d Cir. 1994) ("[T]he government's common law right to recover funds wrongfully paid is well established.").

Based on these longstanding precedents, courts have repeatedly upheld the validity of federal common law claims in cases involving healthcare fraud, including claims for unjust enrichment and payment by mistake. *See U.S. v. Rogan*, No. 02 Civ. 3310, 2006 WL 8427270, at *21-22, 27 (N.D. Ill. Oct. 2, 2006) (awarding judgment to the Government on unjust enrichment and payment-by-mistake claims in the alternative to FCA judgment); *U.S. ex rel. Schiff v. Marder*, 208 F. Supp. 3d 1296, 1318 (S.D. Fla. 2016); *U.S. v. Fadul*, No. 11 Civ. 385, 2013 WL 781614, at *12-15 (D. Md. Feb. 28, 2013); *Ormsby*, 2020 WL 1590521, at *54; *see also Kester VI*, 2014 WL 4401275, at *12 (collecting cases and denying motion to dismiss state unjust enrichment claims pleaded in the alternative by state plaintiffs).

Omnicare erroneously contends that the Government does not explain "its theory of how it made mistaken payments or how Omnicare was unjustly enriched." (Def. Br. at 24.) But theories of "payment by mistake and unjust enrichment" are "in essence . . . alternative pleadings to [the government's] fraud claims under the False Claims Act." *U.S. v. United Techs. Corp.*, 626 F.3d 313, 323 (6th Cir. 2010).[12] As to payment by mistake, the Complaint's allegations supporting its FCA claims amply demonstrate that that "the government made [relevant] payments under an erroneous belief which was material to the decision to pay," such that "it is entitled to recover the payments." *U.S. v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970). The Complaint alleges that Omnicare submitted hundreds of thousands of claims for drugs dispensed without valid prescriptions, but transmitted false information to make it appear that it had valid prescriptions, as federal law required. (Compl. ¶¶ 238-48.) The Government Payors reimbursed

[12] A plaintiff may plead alternative theories of relief, "regardless of consistency." Fed. R. Civ. P. 8(d)(2)-(3). Thus, courts "permit[] the government to proceed with claims alleging FCA violations as well as claims for unjust enrichment or payment by mistake." *U.S. ex rel. Purcell v. MWI Corp.*, 254 F. Supp. 2d 69, 79 (D.D.C. 2003) (collecting cases). This Court has agreed with respect to state law unjust enrichment claims. *Kester VI*, 2014 WL 4401275, at *12.

Omnicare for the claims based on the erroneous belief that the dispensations were supported by valid prescriptions, but would not have made these payments if they were aware that were no such prescriptions. (*Id.* ¶¶ 249-57, 289.)

The Complaint also fulfills the elements of unjust enrichment—that Omnicare knowingly received a benefit from the Government under "circumstances as to make it inequitable for the defendant to retain the benefit without payment of its value." *U.S. v. Bouchey*, 860 F. Supp. 890, 894 (D.D.C. 1994) (quotation marks omitted); *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196 (CM) (JCF), 2014 WL 6655703, at *7 (S.D.N.Y. Nov. 24, 2014) (stating that "doctrine of unjust enrichment" requires a person to "make restitution of or for property or benefits received, retained or appropriated, where it is just and equitable that such restitution be made" (quotation marks omitted)). Omnicare unjustly enriched itself by receiving tens of millions of dollars in payments for dispensations that were not legally authorized. (Compl. ¶¶ 238-48, 292.) These dispensations were not covered by the Federal Healthcare Programs, and Omnicare should be required to return these payments. The Government's allegations are more than sufficient to support its unjust enrichment and payment by mistake causes of action as well. *See, e.g., U.S. ex rel. Forcier v. Computer Scis. Corp.*, 183 F. Supp. 3d 510, 529 (S.D.N.Y. 2016).

Last, the FCA does not displace the Government's federal common law claims. "The False Claims Act is not in derogation of the common law but is merely another remedy which the government can invoke to protect itself from fraud." *Mead*, 426 F.2d at 123 n.4. The elements of the federal common law causes of action "are independent of, alternative to, and have distinct elements of proof from, the Government's claims under the [FCA]." *U.S. v. Crumb*, No. 15 Civ. 655, 2016 WL 4480690, at *17 (S.D. Ala. Aug. 24, 2016). Unlike the FCA, the

theories of payment by mistake and unjust enrichment have no scienter element. So, "even where [the Government] cannot establish that a defendant acted knowingly for purposes of the False Claims Act, [it] may be entitled to recovery under the alternative theory of payment by mistake of fact." *Fadul*, 2013 WL 781614, at *12; *accord Crumb*, 2016 WL 4480690, at *17; *see U.S. v. Applied Pharmacy Consultants, Inc.*, 182 F.3d 603, 605 (8th Cir. 1999). The common law theories at issue here redress different, lesser misconduct that does not involve knowing fraud, and thus lead to lesser penalties—single, instead of treble, damages. There is no sensible reason that "Congress would intend to give the government access to a judicial forum by statute when the overpayment was procured by fraud but to preclude the government from a routine common law damages action for overpayment." *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 17-18 (1st Cir. 2005) (construing Medicare Act).[13]

G. If The Court Determines The Complaint Is Inadequately Pleaded, The Government Requests Leave To Amend

The Government respectfully requests that, if the Court is inclined to hold that any of the claims in the Complaint are inadequately pleaded, the Government be given an opportunity to amend the Complaint to cure the deficiency.

CONCLUSION

For the foregoing reasons, the Court should deny the Defendants' motions to dismiss.

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[13] The out-of-circuit cases Omnicare cites are either not good law or distinguishable. In one case, the court initially rejected an unjust enrichment claim in the basis that the FCA is "an adequate legal remedy to protect the federal government's interests." *U.S. v. Job Res. for the Disabled*, No. 97 Civ. 3904, 2000 WL 562444, at *4 (N.D. Ill. May 9, 2000). But on reconsideration, the court granted summary judgment to the Government on its FCA claim, and held that the unjust enrichment claim was *mooted* by the Government's recovery in full. *U.S. v. Job Res. for the Disabled*, No. 97 Civ. 3904, 2000 WL 1222205, at *4 (N.D. Ill. Aug. 24, 2000). The other case Omnicare cites depends on the availability of contract remedies, which are not at issue here. *See U.S. v. Hydroaire, Inc.*, No. 94 Civ. 4414, 1995 WL 86733, at *6 (N.D. Ill. Feb. 27, 1995); *see also Purcell*, 254 F. Supp. 2d at 78-79 (declining to follow these cases).

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